UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,300	04/09/2004	Paul R. Hinton	011823-012611US	1900

20350 7590 04/13/2007

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
CROWDER, CHUN	
ART UNIT	**PAPER NUMBER**
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,300	HINTON ET AL.	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,13,16,28-33 and 38-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *16 and 28-33* is/are allowed.

6)☒ Claim(s) *1-8,13 and 38-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/07/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed 12/07/2006, has been entered.

2. Applicant's amendments to the claims, filed 03/06/2007, are acknowledged.

Claims 9-12, 14, 15, 17-27, and 34-37 have been canceled.

Claims 1-3, and 5 have been amended.

Upon further consideration and in the interest of compact prosecution, the prior art search have been extended to cover the species of amino acid substitutions at positions 250 and 428 with amino acid residues glutamic acid and phenylalanine, respectively.

Claims 1-8, 13, 16, 28-33, and 38-41 are pending and currently under consideration.

3. Applicant's IDS, filed 12/07/2006, is acknowledged and has been considered.

4. This is a **New Ground of Rejection.** The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8, 13, and 38-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-8, 13, and 38-41 are indefinite because each of the SEQ ID NO of the heavy chain amino acid sequences recited represent one single species of specific amino acid substitutions in either position 250 or 250 and 428 (see Figure 22 of the instant specification). However, independent claims 1, 3, and 5 recite two amino acid substitutions for positions 250 and 428 (e.g. 250 is glutamic acid or glutamine and 428 is leucine or phenylalanine); as such applicant fail to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

6. These are **New Grounds of Rejection**. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-8, 13, and 38-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A) Claims 1, 2, 13, 38, and 39 recite "at least amino acid residue 250 ... and amino acid residue 428 ..., wherein the FcRn binding affinity and/or serum half-life of said modified antibody is altered" and claims 3, 4, 6-8, 40 and 41 recite "a heavy chain constant region substantially identical to that of a naturally occurring claims IgG antibody" as part of the invention.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not provide a sufficient enabling description of the claimed invention. The disclosure appears to show only antibodies with certain specified amino acid substitutions. For example, the specification discloses only an engineered antibody daclizumab with amino acid substitutions in positions 250 and 428 of the Fc region (see Examples on pages 44-95 of the instant specification). The instant claims encompass in their breadth *any* modified daclizumab antibody comprising amino acid substitutions in addition to position 250 and 428.

However, there does not appear to be sufficient guidance in the specification as field as to how the skilled artisan would make and use the claimed modifited anti-CD25 monoclonal antibody that has "at least amino acid residue 250 ... and amino acid residue 428 ..., wherein the FcRn binding affinity and/or serum half-life of said modified antibody is altered" and "a heavy chain constant region substantially identical to that of a naturally occurring claims IgG antibody".

The state of the art at the time the invention was made recognized that certain positions of the Fc region of an IgG antibody, e.g. 310 and 435, must be maintained in order to preserve the sharp pH dependence of the FcRn/IgG interaction. For example, Martin et al. (Molecular Cell 2001. 7:867-877. Reference 68 on IDS) show that mutation in position 435 of the Fc region reduces the binding to FcRn indicating reduced serum half-lives in vivo (see entire article, particularly Results on pages 867-875).

Further, the instant application disclose that not all mutations the Fc region result in desired function, e.g. mutations in position 314 of an antibody show reduced binding to human FcRn (see page 66 of the instant specification). Therefore, only certain positions in the Fc region of an IgG antibody can be altered for enhanced binding to FcRn and increased serum half-life.

Given the extensive variation permitted by the instant claim language, the skilled artisan would not reasonably predict such daclizumab antibody comprising "at least amino acid residue 250 ... and amino acid residue 428 ..., wherein the FcRn binding affinity and/or serum half-life of said modified antibody is altered" and "a heavy chain constant region substantially identical to that of a naturally occurring claims IgG antibody" to have the same function as the instant claimed invention.

B) Claims 1-8, 13, and 38-41 recite "daclizumab" as part of the invention.

As a required element, the antibody "daclizumab" must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the appropriate cell line/hybridoma which produces "daclizumab". See 37 CFR 1.1801-1.1809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in US patent applications.

Amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which case the statement need not be verified. See MPEP 1.804(b).

Alternatively, it is noted that Example 13 on pages 93-94 of the instant specification discloses that daclizumab is a humanized anti-CD25 antibody, which is marketed as Zenapax, wherein the amino acid sequences of the light and heavy chain variable regions are disclosed in U.S. Patent No. 5,530,101, which is incorporated by reference.

Applicant is reminded that to incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where the material is found in the various documents. See Advanced Display Systems, Inc. v. Kent State Univ., 54 USPQ2d 1673 (Fed. Cir. 2000) citing In re Seversky, 177 USPQ 144, 146 (CCPA 1973).

However, upon a review of U.S. Patent NO. 5,530,101, the disclosure of a CD25-specific humanized antibody by the name of daclizumab or Zenapax as disclosed in the instant specification is not readily apparent.

Applicant is invited to clarify the written support for the claimed and disclosed amino acid sequences of the light and heavy chain variable regions of daclizumab of the instant application and its nexus to U.S. Patent No. 5,530,101 by someone in position to corroborate the fact.

If applicant can provide a sufficient nexus between the instant application and U.S. Patent No. 5,530,101 for the claimed light and heavy chain variable regions of daclizumab of the instant application, applicant may be able to rely upon such sequences from U.S. Patent No. 5,530,101 and not have to amend the instant application accordingly.

In addition, if applicant can provide this sufficient nexus, the conditions for the deposit of biological materials under 35 USC 112, first paragraph, enablement for the claimed heavy and light chain variable regions of daclizumab of the instant application may be satisfied.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-8, 13, 15, and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8-12, 19-22, 25-28, 34-43, and 49 of copending USSN: 10/687,118, claims 1-4, 14, and 15 of copending USSN: 11/102, 621, and claims 1-8, 13, 15, and 16 of the copending USSN: 10/966,673.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant and copending claims are drawn to same or nearly the same modified antibodies with the same modifications to the heavy chain constant regions for enhancing FcRn binding affinity and/or increasing serum half-life.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant requests that these provisional obviousness-type double patenting rejections be held in abeyance until the claims are otherwise allowable.

Given that no terminal disclaimer signed by the assignee and fully complied with 37 CFR 3.73(b) was filed, the provisional rejections on the ground of nonstatutory obviousness-type double patenting are maintained.

10. Claims 1-8, 13, 15, and 16 are directed to an invention not patentably distinct from claims 1-3, 5, 7-10, 12, 13, 15, and 17-19 of commonly assigned copending USSN: 10/966,673 for the reasons stated above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned USSN: 10/966,673, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

11. Upon further consideration as well as applicant's amendments, the previous rejection under 35 U.S.C. 103(a) has been withdrawn.

12. Claims 16 and 28-33 appear to be free of the prior art.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
March 13, 2007

PHILLIP GAMBEL, PH.D JD
PRIMARY EXAMINER
TC 1600
3/13/07